MAR 2 6 2012

BioPlex® 2200 ToRC IgG 510(k) Summary

510(k) Number K120572 Date Prepared: March 26, 2012

Introduction

Bio-Rad Laboratories hereby submits this Special 510(k) in accordance with the requirements of SMDA 1990 and 21 CFR 807.92. This summary of 510(k) safety and effectiveness information provides detail as a basis for a determination of substantial equivalence for the BioPlex® 2200 ToRC IgG Panel.

Submitter name, address and contact

Submitter	Contact Person
Bio-Rad Laboratories, Inc BioPlex Division 5500 E. Second Street Benicia, CA 94510	Juang Wang Regulatory Affairs Representative Phone: (510)741-4609 Fax: (510)741-3941

Device name and Classification

BioPlex 2200 ToRC IgG

Classification Name	multiplex flow immunoassay, *T. gondii*, rubella and CMV - Rubella virus serological reagents
Common Name	Multi-Analyte Detection System for *Toxoplasma gondii* IgG, Rubella IgG and Cytomegalovirus (CMV) IgG
Product Trade Name	BioPlex 2200 ToRC IgG on the BioPlex 2200 Muli-Analyte Detection System
Device Class	Class II
Classification Panel	Microbiology
Regulation Number	866.3510
Product Code	OMI, JIX, JJY

Legally Marketed Predicate Device

BioPlex® 2200 ToRC IgG Kit, k080008

INTENDED USE / INDICATIONS FOR USE

BioPlex® 2200 ToRC IgG Kit

The BioPlex 2200 ToRC IgG kit is a multiplex flow immunoassay intended for the quantitative detection of IgG antibodies to *Toxoplasma gondii* (*T. gondii*) and Rubella, and the qualitative detection of IgG antibodies to Cytomegalovirus (CMV) in human serum and EDTA or heparinized plasma.

The ToRC IgG kit is intended for use with the Bio-Rad BioPlex 2200 System.

This kit is intended as an aid in the determination of serological status to *T. gondii*, Rubella and CMV. This kit is not intended for use in screening blood or plasma donors.

Performance characteristics for *T. gondii* and Rubella have not been evaluated in immunocompromised or immunosuppressed individuals. Performance characteristics for CMV have not been evaluated in immunosuppressed or organ transplant individuals. Performance characteristics of this kit have not been established for use in neonatal screening or for use at a point of care.

BioPlex® 2200 ToRC IgG Calibrator Set

The BioPlex 2200 ToRC IgG Calibrator Set is intended for the calibration of the BioPlex 2200 ToRC IgG Reagent Pack.

BioPlex® 2200 ToRC IgG Control Set

The BioPlex 2200 ToRC IgG Control Set is intended for use as an assayed quality control to monitor the overall performance of the BioPlex 2200 Instrument and BioPlex ToRC IgG Reagent Pack in the clinical laboratory. The performance of the BioPlex 2200 ToRC IgG Control Set has not been established with any other *Toxoplasma gondii*, Rubella or Cytomegalovirus (CMV) IgG antibody assays.

Device Description

The BioPlex® 2200 ToRC IgG kit uses multiplex flow immunoassay, a methodology that greatly resembles traditional EIA, but permits simultaneous detection and identification of many antibodies in a single tube. "ToRC" is an acronym for individual tests to detect antibodies to *Toxoplasma gondii* (*T. gondii*), Rubella, and Cytomegalovirus (CMV). Three (3) different populations of dyed beads are coated with cell lysates bearing *T. gondii*, Rubella, or CMV antigens.

The BioPlex 2200 System combines an aliquot of patient sample, sample diluent, and bead reagent into a reaction vessel; the mixture is incubated at 37°C. After a wash cycle, anti-human IgG antibody, conjugated to phycoerythrin (PE), is added to the dyed beads, and this mixture is incubated at 37°C. The excess conjugate is removed in another wash cycle, and the beads are re-suspended in wash buffer. The bead mixture then passes through the detector. The identity of the dyed beads is determined by the fluorescence of the dyes, and the amount of antibody captured by the antigen is determined by the fluorescence of the attached PE. Raw data are calculated in relative fluorescence intensity (RFI).

Three additional dyed beads, Internal Standard Bead (ISB), Serum Verification Bead (SVB) and a Reagent Blank Bead (RBB) are present in each reaction mixture to verify detector response, the addition of serum or plasma to the reaction vessel and the absence of significant non-specific binding in serum or plasma.

The instrument is calibrated using a set of six (6) distinct calibrator vials, the BioPlex 2200 ToRC IgG Calibrator Set. For *T. gondii* and Rubella, six (6) vials, representing six (6) different levels of antibody concentrations, are used for quantitative calibration, and results for patient samples are expressed in IU/mL. For *T. gondii*, results of ≤ 9 IU/mL are negative, 10 and 11 IU/mL are equivocal, and results of ≥ 12 IU/mL are reported as positive. For Rubella, results of ≤ 7 IU/mL are reported as negative, 8 and 9 IU/mL are equivocal, and ≥ 10 IU/mL are reported as positive. For CMV, four (4) vials, representing four (4) different antibody concentrations, are used for qualitative calibration. CMV results are expressed as an antibody index (AI) and results of ≤ 0.8 AI are negative, 0.9 and 1.0 AI are equivocal, and results of ≥ 1.1 AI are reported as positive.

The BioPlex 2200 ToRC IgG Control Set includes a negative control as well as two (2) multi-analyte positive controls. The BioPlex ToRC IgG Low Positive Control contains antibodies for *T. gondii*, Rubella and CMV and the BioPlex ToRC IgG High Positive Control contains antibodies for *T. gondii* and Rubella. The BioPlex ToRC IgG Positive Controls are manufactured to give positive results, with values above the cut-off for each specific analyte. The BioPlex ToRC IgG Negative Control is manufactured to give negative results, with values below the cut-off for each specific analyte. The recommended frequency for performing quality control is once every 24-hour testing period. Performing quality control is also necessary after each new assay calibration and certain service procedures.

Similarities and Differences

Similarities

Feature	Modified Device
Intended Use/Indications For Use	No Change
Kit components	No Change*
Technical Specifications	No Change
Fundamental Scientific Technology	No Change

*Note: No reagent formulation change since clearance

Differences

The only difference of the BioPlex® 2200 ToRC IgG is to modify QC testing from each reagent pack to once per day as stated in the Instructions For Use (IFU) of the BioPlex® 2200 ToRC IgG.

Feature	Modified	Predicate
Frequency of Reagent Pack QC Testing	QC once per day and per new reagent pack lot	QC once per pack and per day

Summary of Design Control Activities

A Failure Mode and Effect Analysis (FMEA) was used to facilitate, capture, and quantify potential impacts of false positive or negative patient results. The Risk Priority Number (RPN) is a quantitative measure of the combined effects of severity, occurrence, and detection of potential risks. Specific mitigations are recommended that may include changes to the design or formulation if the RPN score exceeds a chosen threshold.

The Design Control Activities include Risk Analysis method to identify the verification and validation activities required, test used, and acceptance criteria.

Based on the conclusion of the risk management report, the modified QC procedure fulfills the requirements of the specifications of the design control process. Therefore, the performance of the modified QC test frequency is substantially equivalent to the current cleared kit.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

Bio-Rad Laboratories, Inc.
c/o Mr. Juang Wang
Regulatory Affairs Representative
BioPlex Division
5500 E. Second Street
Benicia, CA 94510

MAR 2 6 2012

Re: K120572
Trade/Device Name: BioPlex 2200 ToRC IgG on the BioPlex 2200 Multi-Analyte Detection System
Regulation Number: 21 CFR 866.3510
Regulation Name: Rubella Virus Serological Reagents
Regulatory Class: Class II
Product Code: OMI, JIX, JJY
Dated: February 24, 2012
Received: February 27, 2012

Dear Mr. Wang:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sally A. Hojvat, M.Sc., Ph.D.
Director
Division of Microbiology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication(s) For Use Statement

510(k) Number (if known): K120572

Device Name: BioPlex® 2200 ToRC IgG Kit
BioPlex® 2200 ToRC IgG Calibrator Set
BioPlex® 2200 ToRC IgG Control Set

Indications for Use:

BioPlex® 2200 ToRC IgG Kit

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Prescription Use __x__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line-Continue on another page if needed)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K120572